DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 30 2002

Kai Hansjurgens, President
Hako-Med
537 Cummins Street
Honolulu, Hawaii 96814

Re: 02P-0187-CP1

Dear Mr. Hansjurgens:

This responds to your citizen petition, dated April 23, 2002, concerning the patient-connected electrode lead wires used with your firm's vasopneumatic device (VacuPulls/VasoPulse). The device is used for powered muscle stimulation and peripheral nerve stimulation for adjunctive use in symptomatic relief of chronic pain. The vacuum hose connects the flexible suction cups to the vasopneumatic device, which creates and controls the vacuum used in conjunction with the treatment of medical conditions. Some of the hoses that terminate on the patient with a vacuum cup incorporate a low voltage electrode that contacts the patient. Your petition requests an exemption from the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) for your vacuum hoses that by design incorporate noncompliant patient-connected electrode lead wires.

You base your request on the argument that unless a vacuum is maintained, the vacuum cups that contact the patient fall away, which breaks the electrical contact. You add that only through some intentional act to fix the patient lead wires in some mechanical manner, would electrical contact be made. Finally, you initially claimed that the Food and Drug Administration (FDA) granted an exemption from the performance standard for a device that uses the same type of connection. You later acknowledged in a letter dated May 23, 2002, that no such exemption was granted by FDA.

I am denying your request for an exemption from the performance standard for the following reasons:

- Your device fails the performance standard requirement because the electrode lead wires will contact a flat conductive surface.
- The electrode lead, which is equivalent to a single pole connector, fails to meet the corresponding conductive finger test.
- The hose connector can be inserted, even by mistake, into the line jack of 240 volt, 50 amperage electrical outlet, which delivers a lethal voltage.

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A hazardous electrical short still remains possible and could be a serious issue if the patient were grounded, such as by touching a bed rail with a wet hand or leg, in the presence of low-voltage (18 volt) leakage currents that may exceed 500 micro amps. Wet skin's resistance to electrical current falls substantially and could result in an electrical shock that causes serious adverse consequences, including respiratory paralysis, fatigue, or pain.

You also rely on the argument that only through an intentional act would an electrode contact a patient and expose them to the risk of electrical shock. You cannot preclude the possibility of a vacuum cup's inadvertent contact with a patient or an instance where a patient may hold a vacuum cup in place. This is a needless exposure to the risk that the performance standard intends to prevent.

You submitted additional information that suggested an independent organization would consider the inclusion of warning statements in the operating instructions to warn against the use of straps, tapes, or other mechanical aids to fix the electrodes on the skin. The preamble to the performance standard addressed the issue concerning the use of warning labels to reduce risk. FDA determined that the continued marketing of unprotected electrode lead wires and patient cables, no matter how they are labeled, presents an unreasonable and substantial risk of illness or injury to individuals.

Your device's failure to meet the requirements of the performance standard needlessly exposes patients to known and preventable risks. You fail to show why your device cannot be designed to meet the performance standard and still accomplish its clinical purpose. In this instance, the public health derives no benefit from the continued use of noncompliant electrode lead wires that is not already provided by equivalent powered muscle stimulator and powered peripheral nerve stimulator devices that use compliant electrode lead wires.

Please respond within thirty (30) days describing the disposition that has been or will be taken concerning VacuPulls/VasoPulse low voltage electrodes that do not meet the performance standard. Your response should be mailed to Kent Berthold at the following address:

Food and Drug Administration
Center for Devices and Radiological Health
Cardiovascular and Neurological Devices Branch, HFZ-341
2098 Gaither Road
Rockville, Maryland 20850

I trust that this is responsive to your request. If additional information is required, please contact Kent Berthold in our Office of Compliance at (301) 594-4648.

Sincerely yours,

Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health